Department of Justice

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ENDO PHARMACEUTICALS AND ENDO HEALTH SOLUTIONS TO PAY $192.7 MILLION TO RESOLVE CRIMINAL AND CIVIL LIABILITY RELATING TO MARKETING OF PRESCRIPTION DRUG LIDODERM FOR UNAPPROVED USES

WASHINGTON – Pharmaceutical company Endo Health Solutions Inc. and its subsidiary Endo Pharmaceuticals Inc. (Endo) have agreed to pay $192.7 million to resolve criminal and civil liability arising from Endo's marketing of the prescription drug Lidoderm for uses not approved as safe and effective by the Food and Drug Administration (FDA), the Justice Department announced today. The resolution includes a deferred prosecution agreement and forfeiture totaling $20.8 million and civil false claims settlements with the federal government and the states and the District of Columbia totaling $171.9 million. Endo Pharmaceuticals Inc. is a Delaware corporation headquartered in Malvern, Pa.

"FDA's drug approval process is designed to ensure that companies market their products for uses that are proven to be safe and effective," said Assistant Attorney General for the Justice Department's Civil Division Stuart F. Delery. "We will hold accountable those who circumvent that process in pursuit of financial gain."

In a criminal information filed today in the Northern District of New York, the government charged that, between 2002 and 2006, Endo Pharmaceuticals Inc. introduced into interstate commerce Lidoderm that was misbranded under the Federal Food, Drug and Cosmetic Act (FDCA). The FDCA requires a company, such as Endo Pharmaceuticals Inc., to specify the intended uses of a product in its new drug application to the FDA. Once approved, a drug may not be introduced into interstate commerce for unapproved or "off-label" uses until the company receives FDA approval for the new intended uses. During the period of 2002 to 2006, Lidoderm was approved by the FDA only for the relief of pain associated with post-herpetic neuralgia (PHN), a complication of shingles. The information alleges that, during the relevant time period, the Lidoderm distributed nationwide by Endo Pharmaceuticals Inc. was misbranded because its labeling lacked adequate directions for use in the treatment of non-PHN related pain, including low back pain, diabetic neuropathy and carpal tunnel syndrome. These uses were intended by Endo Pharmaceuticals Inc. but never approved by the FDA. The information further alleges that certain Endo Pharmaceuticals Inc. sales managers provided instruction to certain sales representatives concerning how to expand sales conversations with doctors beyond PHN and encouraged promotion of Lidoderm in workers' compensation clinics.

In a deferred prosecution agreement to resolve the charge, Endo Pharmaceuticals Inc. admitted that it intended that Lidoderm be used for unapproved indications and that it promoted

Lidoderm to health care providers for those unapproved indications. Under the terms of the deferred prosecution agreement, Endo Pharmaceuticals Inc. will pay a total of $20.8 million in monetary penalties and forfeiture. Endo Pharmaceuticals Inc. further agreed to implement and maintain a number of enhanced compliance measures, including making publicly available the results of certain clinical trials and requiring an annual review and certification of its compliance efforts by the Chief Executive Officer of its parent company, Endo Health Solutions. The deferred prosecution agreement will not be final until accepted by the U.S. District Court for the Northern District of New York.

"The safety and efficacy of drugs must be shown by science, not sales pitches," said U.S. Attorney for the Northern District of New York Richard S. Hartunian. "Drugs marketed for intended uses not approved by the FDA are misbranded because their labeling lacks adequate directions for those uses. This settlement emphasizes that public health is protected by labeling based on product performance, rather than profitability, and promotes enhanced efforts to ensure compliance with all requirements."

In addition, Endo agreed to settle its potential civil liability in connection with its marketing of Lidoderm. The government alleged that, from March 1999 through December 2007, Endo caused false claims to be submitted to federal health care programs, including Medicaid, a jointly funded federal and state program, by promoting Lidoderm for unapproved uses, some of which were not medically accepted indications and, therefore, were not covered by the federal health care programs. Of the $171.9 million Endo has agreed to pay to resolve these civil claims, Endo will pay $137.7 million to the federal government and $34.2 million to the states and the District of Columbia.

"Off-label marketing can undermine the doctor-patient relationship and adversely influence the clear and honest judgment of doctors that their patients rely on and trust," said U.S. Attorney for the Eastern District of Pennsylvania Zane D. Memeger. "Pharmaceutical companies have a legal obligation to promote their drugs for only FDA-approved uses. This obligation takes precedence over the company's bottom line."

"The settlement announced today demonstrates the government's continued scrutiny of pharmaceutical companies that interfere with FDA's mission of ensuring that drugs are safe and effective for the American public," said Special Agent in Charge of the FDA's Office of Criminal Investigations' New York Field Office Mark Dragonetti. "We will continue to work with our law enforcement partners to investigate and prosecute pharmaceutical companies that disregard the drug approval process and jeopardize the public health by engaging in the nationwide distribution of misbranded products."

"Endo Pharmaceutical enriched themselves at the expense of the public," said Special Agent in Charge Andrew W. Vale of the Albany Division of the Federal Bureau of Investigation. "Patients will search for drug therapies to assist in pain management, and they deserve the right to drugs approved for such use. The FBI will continue to work with our federal partners to investigate companies such as Endo Pharmaceuticals to ensure patients are safe."

Also as part of the settlement, Endo Pharmaceuticals Inc. has agreed to enter into a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General that requires Endo to implement measures designed to avoid or promptly detect conduct similar to that which gave rise to this resolution. Among other things, the CIA requires Endo to implement an internal risk assessment and mitigation program and requires numerous internal and external reviews of promotional and other practices. The CIA also requires key executives and individual board members to sign certifications about compliance, and it requires the company to publicly report information about its financial arrangements with physicians.

"By marketing Lidoderm for uses not covered by federal health care programs, Endo profited at the expense of taxpayers and could have put patients at risk," said Inspector General of the U.S. Department of Health and Human Services Daniel R. Levinson. "Under our CIA, Endo agrees to promote its products legally, while board members and top executives are specifically held accountable for compliance."

The civil settlement resolves three lawsuits pending in federal court in the Eastern District of Pennsylvania under the *qui tam*, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the government and to share in any recovery. The actions were filed by Peggy Ryan, a former Lidoderm sales representative, Max Weathersby, another former Lidoderm sales representative and Gursheel S. Dhillon, a physician. The whistleblowers' share of the settlement has not been determined.

This settlement illustrates the government's emphasis on combating health care fraud and marks another achievement for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Secretary of Health and Human Services Kathleen Sebelius. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in this effort is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than $19 billion through False Claims Act cases, with more than $13.4 billion of that amount recovered in cases involving fraud against federal health care programs.

The civil settlement was handled by the U.S. Attorney's Office for the Eastern District of Pennsylvania and the Civil Division's Commercial Litigation Branch. The criminal case was handled by the U.S. Attorney's Office for the Northern District of New York and the Civil Division's Consumer Protection Branch. These matters were investigated by the Federal Bureau of Investigation, the Food and Drug Administration Office of Criminal Investigation, the Department of Health and Human Services Office of Inspector General Office of Investigations, the Defense Criminal Investigative Service of the Department of Defense, the U.S. Postal Service Office of Inspector General and the Office of Personnel Management Office of Inspector General with assistance from the Department of Health and Human Services Office of Counsel to the Inspector General and Office of General Counsel and Center for Medicare and Medicaid Services, the Food and Drug Administration's Office of Chief Counsel and the National Association of Medicaid Fraud Control Units.

Except as to conduct admitted in connection with the deferred prosecution agreement, the claims settled by the civil agreement are allegations only, and there has been no determination of civil liability. The civil lawsuits are captioned *United States ex rel. Ryan v. Endo Pharmaceuticals Inc.,* Civil Action No. 05-cv-3450, *United States ex rel. Weathersby, et al. v. Endo Pharmaceuticals Inc., et al,* Civil Action No. 10-cv-2039 and *United States ex rel. Dhillon v. Endo Pharmaceuticals,* Civil Action No. 11-cv-7767, all docketed in the Eastern District of Pennsylvania.

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